

Message

From: Culleen, Lawrence E. [Lawrence.Culleen@arnoldporter.com]
Sent: 12/18/2019 7:59:50 PM
To: Barone, Stan [Barone.Stan@epa.gov]
CC: Fehrenbacher, Cathy [Fehrenbacher.Cathy@epa.gov]
Subject: Following up on NMP / PBPK code

Stan, Cathy --

We very much appreciate gaining access to various Excel Spreadsheets today through the Agency's website for the NMP draft Risk Evaluation's use of the PBPK Modeling.

In conferring with the scientists with whom I am working, I'm advised the spreadsheets are helpful to them, but they remain unable to discern exactly how the Agency's risk assessment team that used the PBPK model for NMP purposes, adjusted the historical commercial version of the program to make it suitable for the purposes of the most recent draft Risk Evaluation for NMP.

Apparently, the commercially available version of the program is no longer being supported. Thus, we are trying to make do using a version our consultants have at their disposal, which we want to be certain conforms with the program as it was adjusted by EPA. The reason is, we want to be certain the consultant's assumptions and tweaks to the program (if any are needed) will accurately mimic the Agency's. Apparently, to do this accurately, I am told the consultants would want access to a copy of the ".m script file" or the ".csl or ACSL model file" which is not among the materials that were posted today.

It might be much simpler if the technical consultants can reach out directly to someone at EPA who is familiar with the programming as well as the files that were released today. I can provide examples of the kinds of files we are seeking (based on the 2016 Poet paper to which I believe reference is made in the draft Risk Evaluation).

Is there someone on your team to whom I can refer the consultants?

I'd like to have Ken Unice, from CARDNO CHEMRISK, speak directly with someone you'd recommend (or vice versa). Ken's coordinates are: Work +1 412 694 7050 and Email ken.unice@cardno.com www.cardnochemrisk.com.

Thanks again; sorry to be a pest on this issue.

Larry

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From: Culleen, Lawrence E.
Sent: Wednesday, December 18, 2019 8:38 AM
To: Wolf, Joel

Cc: Barone, Stan; Mark A. Hartman; Fehrenbacher, Cathy

Subject: Re: gaining access to NMP / PBPK code

Thanks Joel.

I'd be glad to work directly with whomever can assist to arrange the pick up of a thumb drive or CD if that would work.

Larry

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From: "Wolf, Joel" <Wolf.Joel@epa.gov>

Sent: Wednesday, December 18, 2019 7:22 AM

To: Cullen, Lawrence E.

Cc: Barone, Stan; Hartman, Mark; Fehrenbacher, Cathy

Subject: Re: gaining access to NMP / PBPK code

External E-mail

Thanks for the note and good to see you as well Larry. Let me discuss with Stan and Cathy in the morning to see what we can figure out.

Sent from my iPhone

On Dec 17, 2019, at 6:24 PM, Cullen, Lawrence E. <Lawrence.Cullen@arnoldporter.com> wrote:

Joel,

It was good seeing you again today during our meeting with Lynn and Alex during which the Consortium discussed issues of importance to the semiconductor industry.

I noted when I got back to the office late today that a new item has been added to the e-docket for the NMP draft Risk Evaluation that appears to be potentially related to our request for access to the background materials needed to understand and interpret the human exposure (workplace) PBPK

analysis. It appears from Cathy's note to the file that a CD may have been placed in the public reading room for the NMP docket. See attached.

You might recall, and I am sure Stan will remember, that gaining such access was an issue we have been raising with key EPA staff even prior to the SACC meeting. During the Peer Review session, we were led to believe the Semiconductor Industry Association (SIA) would be given access to the files we have expressed interest in reviewing. The attached note implies the files can be readily reduced to a CD. Based on the exchanges EPA personnel had with the Peer Reviewers, perhaps we can conclude the Agency also is planning to distribute a similar CD to SIA?

I would be very happy to personally come back to the Agency's offices again tomorrow to pick up a copy of such a CD if one can be released to me on behalf of SIA. I am sure you recognize that the SIA scientists and consultants with whom we are working are not able to travel to Washington to personally sit in the public docket reading room to painstakingly review the numerous data files using a shared copy of a public version of a CD.

I am not aware that the public reading room personnel have the capacity to make copies of the CD on a "real-time" basis.

Can a member of your staff or Stan's team let me know how we can retrieve a copy of the CD for SIA's use?

Sorry to have to bother you with this request, but we very much want to get the CD to make use of it before it is too late to offer meaningful comments.

Larry

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From: Culleen, Lawrence E. <Lawrence.Culleen@arnoldporter.com>

Sent: Monday, December 16, 2019 5:56 PM

To: hartman.mark@epa.gov

Cc: joel wolf (Wolf.joel@Epa.gov) <Wolf.joel@Epa.gov>; Stanley Barone (Barone.stan@epa.gov) <Barone.stan@epa.gov>

Subject: NMP Risk Evaluation

Gents --

My clients at the Semiconductor Industry Association submitted the attached request for an extension of the comment period for the draft Risk Evaluation for NMP. Thus far, we have not received a reply. Can you let me know if this is being considered favorably?

We are still struggling to try to get the data and Excel files related to the PBPK modeling for NMP exposures that were discussed in the SAAC meeting. It appears that the files have not been made available in the public docket. If I am mistaken in that regard, please advise how I can locate the files. If the files are not yet available to the public, I am hoping one of you might be able to assist me in this regard and also advise whether the extension request will be granted.

Thank you. I look forward to hearing from you.

Larry

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